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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,808	04/26/2005	Yoram Palti	P-5488-US	8892

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EXAMINER	
SINGH, SATYENDRA K	

ART UNIT	PAPER NUMBER
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,808	PALTI ET AL.	
	Examiner	Art Unit	
	SATYENDRA K. SINGH	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-25,30-33 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-25,30-33 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/23/09 has been entered.

Claims 1-21, 26-29, 34 and 35 have been previously canceled.

Claims 22-25, 30-33 and 36 (applicant's elected invention of **Group III**), as currently amended, are examined on their merits in this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 22-25, 30-33 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 22 (as currently amended) recites the limitation of "*inserting an autonomous in vivo sensing device into an upper gastrointestinal tract of a patient, said device comprising a pH-sensitive color-changing material placed on **a** device's optical window and a **magnetic element***", which is confusing. First, it is not clear if the "pH-sensitive color-changing material" is placed on the same device or some other device. Second, it is unclear if the pH-sensitive color-changing material is placed on said "device's optical window and a magnetic element", or if the pH-sensitive color-changing material is placed on said

device's optical window, wherein the device further comprises a magnetic element whose position is not specified in the claim. The instant disclosure (see specification, the only disclosure for a "magnetic element" on page 9, lines 20-22, in particular) or applicant's response (see page 5, 2nd paragraph, in particular) does not provide adequate description for exact location of the "magnetic element" in said device used for the method as claimed. Thus, to a person of ordinary sill in the art, it would not be clear as to where and how the components recited in the amended claim are spatially disposed (see figure 1A, in particular), especially in view of the specification that does not provide for the structural relationships of the "pH-sensitive color-changing material" and "magnetic element". Appropriate explanation/correction is required.

Since, claims 23-25, 30-33 and 36 depend from claim 22, they are also rejected under 35 U.S.C. 112, second paragraph, as being **indefinite** for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names **joint inventors**. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 22-25, 30-33 and 36 (as currently amended) are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall (US 6,228,605 B1; IDS) in view of Iddan et al (US 5,604,531; IDS) and Ishiyama et al (2002; [U]).

Claims are directed to a method for *in vivo* detection of *H. pylori* the method comprising: inserting an autonomous *in vivo* sensing device into an upper gastrointestinal tract of a patient, said device comprising a pH-sensitive color-changing material placed on a device's optical window and a magnetic element; moving the autonomous *in vivo* device to contact at least one location of the upper gastrointestinal tract by an external magnetic field which moves said magnetic element; sensing pH at the location of the upper gastrointestinal tract using said pH-sensitive color-changing material; processing pH data sensed to determine presence of *H. pylori*; and transmitting pH data to an external receiving unit. (see claims 23-25, 30-33 and 36)

Marshall (IDS) discloses a method for *in vivo* detection of *H. pylori* comprising inserting an autonomous *in vivo* sensing device (an endoscope; see abstract, figure 1, and summary of the invention, columns 3-6, in particular) into an upper gastrointestinal tract; sensing pH in at least one location in the upper gastrointestinal tract using said endoscope; and transmitting pH data visually through said endoscope to an external receiving unit (the viewer, for example); wherein the method further comprising indicating a pH value which is about equal to or exceeds a predetermined threshold; wherein sensing pH is by imaging (i.e. visual determination taken as imaging) a color changing pH indicator; the method according to claim 23, wherein the pH value is about 5.5 (see use of pH indicators such as bromothymol blue and phenol red; column

columns 3-6, in particular). The method further comprising visually imaging the gastrointestinal tract using said endoscope, wherein the step of transmitting pH data further comprises transmitting image data (i.e. visual inspection/transmission through an endoscope); the method further comprising ingesting urea prior to inserting the endoscope (see column6, 3rd paragraph, in particular); the method further comprising the step of causing the endoscope to contact at least one location of a stomach mucus by positioning a patient to achieve substantial covering of the patient's stomach (see *in vivo* detection of *H. pylori* using an endoscope, urea and pH indicators, as explicitly disclosed by Marshall on columns 3-6, and claims, in particular).

However, the method, wherein the device is an "**autonomous** *in vivo* sensing device", said device comprising a pH-sensitive color-changing material placed on a device's optical window and a **magnetic element**; **moving** the autonomous *in vivo* device to contact at least one location of the upper gastrointestinal tract by **an external magnetic field** which moves said magnetic element; and wherein the transmitting is done **by radio frequency**, is not explicitly disclosed by the invention of Marshall.

Iddan et al (IDS) disclose an **autonomous video endoscope** that includes a swallowable capsule (including a camera system, an optical system and window for viewing and imaging an area of interest, such as upper GI tract; see column 3, in particular), a transmitter and a reception system, wherein the transmitter transmits the video output of the camera system and the reception system receives the transmitted video output using **radio frequency** (see Iddan et al, abstract, figure 1, 3B, and 5; column 1 and 3; and summary of the invention, in particular). In addition, Iddan et al clearly suggest that "*the capsule can traditionally include sensor elements for measuring pH, temperature, pressure, etc. These sensor elements are described in the prior art*"(see Iddan et al, column 3, lines 38-41, in particular, and column 3 in general).

Ishiyama et al [U] disclose use of magnetic materials (i.e. magnetic elements or magnetic micromachines, made of materials such as NdFeB magnet) that can be moved using an external

magnetic field and can be applied in combination with various devices that are useful in biomedical applications such as catheters, etc. In addition, Ishiyama et al clearly suggest the use of said magnetic elements that can work without the use of wire (i.e. autonomously; see abstract, introduction, and summary, figures 1 and 9, in particular). Thus, use and benefits of magnetic elements that can be incorporated in wireless medical devices and can be moved, in side the body cavities, using an external magnetic field has been fully disclosed and contemplated by Ishiyama et al.

Thus, given the detailed disclosure for a method for *in vivo* detection of *H. pylori* in a patient or subject as disclosed by Marshall, at the time this invention was made, it would have been obvious for a person of ordinary skill in the art to modify the method of Marshall by 1) replacing or substituting the endoscope (i.e. the device) used by Marshall with a better device (i.e. a better functional analogue) disclosed by Iddan et al that works autonomously (by incorporating suitable CCD camera and optical systems having viewing window) using radio frequency to receive and transmit image signal as explicitly disclosed by the invention of Iddan et al (see Iddan et al, column 1, in particular); and 2) by incorporating a magnetic element (as explicitly taught by Ishiyama et al above) in the capsule or device such that it can be moved in the upper GI tract using an external magnetic field for sensing the change in pH at the intended site.

A person of ordinary skill in the clinical art would have been motivated to upgrade the method of Marshall as 1) Iddan et al disclose the potential benefits (i.e. the flexibility to move in the body cavities by its own weight, option of imaging the entire digestive tract and hard to reach parts without discomfort associated with older endoscopes; see Iddan et al, column 1,

Background of the Invention, in particular) of using such independent devices that can be contained in a capsule, and that have all the required components to provide the capability of sensing internal pH, viewing and acquiring pH data using the color change of the pH indicators in the form of an image data, and storing and transmitting said data using RF signals, wherein the data can be further correlated with the presence and/or absence of the microbe, *H. pylori* as explicitly disclosed by Marshall's invention; and 2) Ishiyama et al clearly suggest the benefits of magnetic elements that can be incorporated in wireless medical devices to provide mobility and maneuverability inside the body cavity (such as upper GI tract) or body fluids, using an external magnetic field.

Therefore, such beneficial modifications would have been clearly within the perception of an artisan of ordinary skill in the clinical art at the time this invention was made, and the artisan would have had a reasonable expectation of success when modifying the method of Marshall, and using such autonomous device (in place of older endoscopes that could not function independently) as Iddan et al clearly provide use for such an autonomous video endoscope (see figure 6, and summary of the Invention, in particular); and as Ishiyama et al clearly demonstrate the use and benefits of magnetic elements (in the form of magnetic micromachines) that can be incorporated in medical devices and can be moved and operated/controlled using an external magnetic field without any need of wired systems (i.e. wirelessly). Since, the benefits accrued by incorporating such modifications in the method of Marshall would have been fully contemplated by an artisan of ordinary skill in the medical art at the time this invention was made, in view of the combined teachings of Iddan et al and Ishiyama

et al, the invention as claimed fails to distinguish itself over the cited prior art references of record, and is therefore, considered obvious.

Given the detailed disclosure of Iddan et al for the autonomous device used for sensing pH, temperature, pressure, etc. (see Iddan et al, column 3, in particular), the limitations of claim 22, wherein the pH-sensitive color-changing material is **placed on a device's optical window**, would have been clearly obvious to a person of ordinary skill in the art at the time this invention was made. Iddan et al provide detailed disclosures for the autonomous system that has viewing window, optical system, light source, mirror, CCD camera, etc. that are needed to detect and image the color change using the viewing window of said device, and transmit such signals using radio frequency to an external receiving unit. Thus, given the combined disclosure of Marshall for color changing materials (see Marshall, abstract, in particular, and discussion above) and the autonomous device having an optical window (see Iddan et al) that can wirelessly image and transmit signals to indicate any change in color at the desired location in the upper GI tract such as stomach, such adjustments (for example, placement of pH-sensitive color-changing material on the device's optical window) would have been a common sense approach to a method fully contemplated by an artisan of ordinary skill in order to image the material in question (i.e. in order to detect the changes in color of the pH-sensitive materials), and therefore, it would have been obvious to place the color-changing material where it is in full view of the imager (i.e. on the optical window) as this is well known in the art of endoscopic procedures.

Thus, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill in the clinical art at the time the claimed invention was made.

As per MPEP 2144.06, In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. In re Ruff, 256 F.2d 590, 118 USPQ 340 (CCPA 1958).

As per MPEP 2111.01, during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 22-25, 30-33 and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-21 of copending Application No. 10/524,553 (common inventor, same assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims in said co-pending application are also directed to a similar subject matter as follows:

> "A method for in vivo analysis, the method comprising the steps of: obtaining a sample from a body lumen; combining in vivo the sample with agglutinative particles; and detecting at least one optical change in the combined sample."

Since, the disclosure of co-pending application specifically states that "*the agglutinated particles may include cells, such as bacteria (e.g. H. pylori)*" (see co-pending application, page 4, paragraph [0034], in particular), the two sets of claims are clearly co-extensive in scope, and therefore, a obviousness-type double patenting rejection is required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to ODP Arguments

Regarding the ODP rejection record, since applicants have deferred a response at the present time till an allowable subject matter is identified through prosecution (see remarks, page

6, 1st paragraph), and since, no terminal disclaimer or a pertinent argument has been provided, the rejection of record is deemed to be proper and is therefore, maintained.

Response to Arguments for 103a Rejection

Applicant's arguments filed on January 23rd 2009 (as they pertain to pending claims 22-25, 30-33 and 36 over the cited prior art references of record) have been fully considered but they are **moot** in view of new rejections made in this office action.

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SATYENDRA K. SINGH whose telephone number is (571)272-8790. The examiner can normally be reached on 9-5MF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Satyendra K. Singh/
Examiner, Art Unit 1657

/Irene Marx/
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